K071217

MAY 17 2007

510(K) SUMMARY
(As required by 21 CFR 807.92(a))

A. Submitter Information

Company:
Verathon Inc.
21222 30th Drive SE, Suite 120
Bothell, WA 98041
Phone: 425-867-1348 ext.1350
Fax: 425-883-2896
Email: rgarrison@verathon.com
Contact: Russ Garrison
Acting Director, Regulatory Affairs
Date: April 19, 2007

B. Device Information

Trade/Proprietary Name: Verathon Inc. BladderScan® BVI 9400 Ultrasound System

Common Name: Diagnostic Ultrasound System with Accessories

Classification Name(s):

Regulatory Class: II
Review Category: Tier II
Classification Panel: Radiology
Ultrasonic Pulsed Echo Imaging System
- FR Classification 892.1560
- Product Code 90-IYO

Diagnostic Ultrasound Transducer
- FR Classification 892.1570
- Product Code 90-ITX

Predicate Device: Verathon BladderScan® BVI 6100 Ultrasound System (K022153)

	Device Description:	The Verathon Inc. BladderScan® BVI 9400 Ultrasound System is a portable, battery powered, software controlled ultrasound system used to acquire and display real time B-mode images of the bladder. The system is intended to non invasively monitor bladder volume on an intermittent basis. The system is an effective, low cost, simple to use option for use in a clinical hospital or nursing home setting or for home use under medical supervision.
	Intended Use:	New device: The BladderScan® BVI 9400 is intended to project ultrasound energy through the lower abdomen of the nonpregnant patient to obtain an image of the bladder and uses that image to calculate the bladder volume noninvasively. The BladderScan® BVI 9400 is contraindicated for fetal use and for use on pregnant patients.
C.	Comparison of Required Technological Characteristics:	The Verathon Inc. BladderScan® BVI 9400 Ultrasound System and its integrated 3.0 MHz mechanical sector transducer operate only in B-mode to locate and automatically measure bladder volume. The same transducer is driven at 1.74 MHz to obtain a second harmonic for enhanced bladder wall detection. Bladder volume, patient gender, non optimal directional aiming, battery status, and usage rate indicators are all displayed on the Verathon Inc. BladderScan® BVI 9400 Ultrasound System scanner. The ultrasonic power transmitted the system is not user adjustable. The portable Verathon Inc. BladderScan® BVI 9400 Ultrasound System is applied to the patient's abdomen with a single patient use Sontac® hydrogel pad, manufactured by Verathon Inc. BladderScan® BVI 9400 Ultrasound System. The transducer collects cross-sectional images of the bladder from twelve (12) scan planes. From this information, the Verathon Inc. BladderScan® BVI 9400 Ultrasound System constructs a finite element model of the bladder and automatically computes the volume of urine via volumetric integration. In order to demonstrate the BladderScan® accuracy claimed in 0270-0307 -xx-55, a third party vendor was contracted to build tissue equivalent phantoms with known dimensions. The supplier, Computerized

Imaging Reference Systems (CIRS) is known for supplying medical imaging phantoms to the medical marketplace.

The BladderScan Phantom is essentially a balloon which gets filled with urine mimicking material and then the filled balloon is surrounded with tissue mimicking material. Both the tissue and urine mimicking material have been used by CIRS for many years in bladder volume phantoms.

During the manufacturing process, CIRS measures key parameters of the physical parts as the parts are constructed. These measurements are all NIST traceable and each phantom comes with a certification sheet listing the measurements.

These results obtained through the Verathon Inc. BladderScan® BVI 9400 Ultrasound System are compared to the expected results derived from the NIST traceable measurements. In addition to these measurements, additional measurements are taken by standard ultrasound systems, such as the Sonosite 180, to compare bladder mass measurements.

Accuracy has been demonstrated by comparing CIRS measurements to the measurements of the Verathon Inc. BladderScan® BVI 9400 Ultrasound System.

A Calibration Targeting System, consisting of a heli-coil shaped calibration target along with a specially designed container, allows the user to easily scan a known geometrically shaped target. Data may be optically transmitted to a remote location when connected to the clinician's personal computer via a communication cradle. Connection to this communication cradle allows for battery charging, remote calibration, usage monitoring, software updates, and data transfer through a web-based interface, referenced as ScanPoint®. The Verathon Inc. BladderScan® BVI 9400 Ultrasound System also includes a universal charger cradle for the replaceable lithium ion battery incorporated into the portable instrument.

D.	Summary and Conclusion of Non Clinical and Clinical Testing	All clinical and non clinical testing of the Verathon Inc. BladderScan® BVI 9400 Ultrasound System indicate that the Verathon Inc. BladderScan® BVI 9400 Ultrasound System is substantially equivalent to the Verathon Inc. BladderScan® BVI 6100 Ultrasound System, and all acoustic measurements remain within Preamendment limits.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Verathon, Inc.
c/o Mr. Morten Simon Christensen
Staff Engineer & FDA Office Coordinator
Medical Device Services
Underwriters Laboratories, Inc.
455 East Trimble Road
SAN JOSE CA 95131-1230

MAY 17 2007

Re: K071217
Trade/Device Name: BladderScan® BVI 9400 Ultrasound System
Regulation Number: 21 CFR §892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO and ITX
Dated: April 30, 2007
Received: May 2, 2007

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the BladderScan® BVI 9400 Ultrasound System as described in your premarket notification:

Transducer Model Number

3.0/1.74 MHz Second Harmonic Transducer

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may

publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Andrew Kang, M.D. at (240) 276-3666.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

510(k) Number (if known): ~~New Submission~~ K071217

Device Name: Verathon Inc. BladderScan® BVI 9400 Ultrasound System

Indications for Use:

- Abdomen, B-Mode, per Indications for Use Ultrasound Form
- The BladderScan® BVI 9400 is intended to project ultrasound energy through the lower abdomen of the nonpregnant patient to obtain an image of the bladder and uses that image to calculate the bladder volume and bladder wall mass noninvasively.

Contraindications:

- The BladderScan® BVI9400 is contraindicated for fetal use and for use on pregnant patients.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K071217

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: BladderScan® BVI 9400 Ultrasound System

3.0 / 1.74 MHz Second Harmonic Transducer

K 071217

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Abdominal organs and vascular)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicles)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
	Peripheral vessel							
	Other (Bladder)	N						

N= new indication; P= previously cleared by FDA (K022153)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

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and Radiological Devices
510(k) Number K071217

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K071217

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Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P						
	Intra-operative (Abdominal organs and vascular)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicles)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA (K022153)

Prescription Use (Per 21 CFR 801.109)

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